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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517

62644 7590 07/27/2010

MEDTRONIC

Attn: Noreen Johnson - IP Legal Department

2600 Sofamor Danek Drive

MEMPHIS, TN 38132

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,900	MCKAY ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 27, 45-47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19, 27, 45-47, 49 and 50 is/are allowed.
- 6) ☒ Claim(s) 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal request filed on 3/22/10, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775

Response to Arguments

Applicant's arguments, see appeal request, filed 3/22/10, with respect to the rejection(s) of claim(s) 51-53,56-58 under 35 U.S.C. 102 (a) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn along with that of claims 17-19,27,45-47,49,50, 54,55 under 35 U.S. C. 103(a) also. However, upon further consideration, a new ground(s) of rejection is made in view of Staskin et al. (2002/99258) pertaining to claims 51-58.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51,52,56 are rejected under 35 U.S.C. 102(b) as being anticipated by Staskin et al. (2002/99258). Staskin et al. discloses a length (paragraph 114) of natural tissue (paragraph 121) sized for implantation and having a first end and a second end, paragraph 119. The device is fully capable of implantation in the disc nucleus. Fig. 1 shows a drawstring **66** secured to the length of natural tissue at or near the first end thereof and passes through the tissue from one side thereof to another at a multiplicity of sites **61** at predetermined intervals along the length of the tissue, exiting the tissue at or near the second end thereof and extending beyond said second end to terminate in an end portion. Staskin et al. disclose the drawstring is adapted to being pulled, paragraphs 118.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 57,58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (2002/99258). Staskin et al. is explained supra. However, Staskin et al. does not explicitly disclose the number of sites in which the drawstring passes through is five or ten sites. It would have been obvious to one of ordinary skill in the art at the time of the invention to place the drawstring in at least five or at least ten sites in the natural tissue in the device of Staskin et al. such that it would be of the same length as the tissue. One of ordinary skill in the art would use a larger piece of tissue when the patient is larger than the normal individual thus requiring a bigger piece of tissue and Staskin et al. states (paragraph 118) the length of the drawstring is to be the length or longer than the tissue, thus it would require more sites to secure to the tissue.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (2002/99258) in view of Gabbay (WO 02/39889). Staskin et al. is explained above. However, Staskin et al. fail to disclose the natural tissue is pericardium. Gabbay teaches (Fig. 7) that natural tissue (pericardium) can be used to form a spinal disc device, page 8, lines 17,18. Pericardium, being a well known implant material, is elastic and resilient and suitable for spinal disc replacement, Gabbay, page 7, lines 9-14. It would have been obvious to one of ordinary skill in the art to utilize pericardium as taught by Gabbay for the natural tissue in the Staskin et al. implant because of its suitability and resiliency.

Claims 54,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (2002/99258) in view of Sybert et al. (2002/107570). Staskin et al. is explained above.

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However, Staskin et al. fail to disclose the natural tissue is SIS or braided construction. Sybert et al. teach that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. Sybert additionally teaches that braided construction can be used in tissue implants for providing greater strength, paragraphs 67-70,72. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Staskin et al. implant because of the abundance of SIS and its durability. Additionally it would have been obvious to one of ordinary skill in the art to use braided constructions as taught by Sybert et al. for the implant of Staskin et al. such that it increases the strength of the prosthesis to better stabilize the support it provides.

Allowable Subject Matter

Claims 17-19, 27, 45-47, 49, 50 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jones (3610243) discloses an implantable device formed of "natural" tissue paper material and has a pleated structure with a drawstring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738